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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/588,525	06/06/2000	Manuel de Jesus Arana Rosainz	294-83	8985

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HOFFMANN & BARON, LLP  
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EXAMINER
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SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/588,525

### Applicant(s)

ARANA ROSAINZ ET AL.

### Examiner

Khatol S Shahnan-Shah

### Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 85-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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***DETAILED ACTION***

1. Applicants' amendments and response to non-final action of July 1, 2003, received November 5 2003 is acknowledged. Claims 37-84 have canceled. New claims 85-99 have been added. Specification pages 1 and 12 have been amended.

2. Currently claims 85-99 are pending and under consideration.

***Drawings***

3. Objection to the drawings made in paragraph 4 of the office action mailed July 1, 2003 is withdrawn. Applicants have submitted new formal drawings.

***Abstract***

4. Objection to the specification made in paragraph 5 of the office action mailed July 1, 2003 is withdrawn. Applicants have submitted An abstract on a separate sheet.

***Information Disclosure Statement***

5. Applicants' information disclosure statement received October 6 2003 is acknowledged. The references have been considered by the examiner. See attached 1449.

***Priority***

6. Objection to the specification made in paragraph 7 of the office action mailed July 1, 2003 in regard to priority statement is withdrawn in view of applicants' amendments.

***Specification***

7. Objection to the specification made in paragraph 8 of the office action mailed July 1, 2003 is withdrawn in view of applicants' amendments.

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***Rejections Moot***

8. Rejection of claims 37-70 under 35 U.S.C. 112, first paragraph made in paragraph 10 of the office action mailed July 1, 2003 is moot in view of applicants' cancellation of the claims.

9. Rejection of claims 37-70 under 35 U.S.C. 112, second paragraph made in paragraph 12 of the office action mailed July 1, 2003 is moot in view of applicants' cancellation of the claims.

***New Rejections***

***Claim Rejections - 35 USC § 101***

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 85-99 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Because the claims recite a peptide which read on products of nature and thus unpatentable to applicant. The claims contain no recitation of "isolation" or "purification" to identify a product that is not found in nature. See MPEP 2105.

***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 85-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 85 recites, "wherein the peptide is derived from SEQ ID NO: 1". It is unclear from which portion of SEQ ID NO: 1 this peptide is derived. Furthermore, it is unclear if the derivative has 100% homology to the full length, or if the limitation of being a derivative would include substitutions, deletions and additions to the SEQ ID NO: 1.

It is not clear what applicants intend in recitation of "non-natural homologous amino acid" in claim 89. The term is not defined by the claim or in the specification.

It is not clear what applicants intend in recitation of "backbone-mimetic organic entities" in claim 93. The term is not defined by the claim or in the specification.

Claim 93 recites the limitation "the chain backbone" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 98 is indefinite as being depending from canceled claim 37.

Claims 86-88, 90- 92, 94-97 and 99 are rejected as being depending from indefinite claim 85.

#### ***Claim Rejections - 35 USC § 102***

**14.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**15.** Claims 85-88, 91 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Gazzano-Santoro et al. (US Patent 5, 731,415).

Claims are drawn to a LPS binding protein, which is derived from SEQ ID NO 1.

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Gazzano-Santoro et al. teach a LPS binding protein, which is derived from SEQ ID NO 1. (see attached sequence alignment Accession Number AAW 40153). Gazzano-Santoro et al. teach biologically active LPS binding protein derivatives, which are characterized by the ability to bind and neutralize LPS. (see abstract and column 28, example 23). Gazzano-Santoro et al. teach both N and C terminal regions (see columns 1, 4 and 6). Gazzano-Santoro et al. teach label assays (see column 8). The prior teach the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed proteins and the proteins of the prior art (i. e., that the proteins of prior art does not possess the same material structure and functional characteristics of the claimed proteins). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### ***Conclusion***

16. No claims are allowed.

17. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

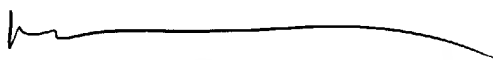
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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January 22, 2004

  
JAMES HOUSEL  
SUPERVISOR  
TECHNOLOGY CENTER 1600  
1/26/04